



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/594,596      | 06/15/2000  | Scott E. Andersen    | 38-21(15878)B       | 7446             |

7590 06/28/2002

Lawrence M Lavin Jr Esq  
Monsanto Company  
Patent Department E2NA  
800 N Lindbergh Boulevard  
St Louis, MO 63167

EXAMINER

ARTHUR, LISA BENNETT

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1634

DATE MAILED: 06/28/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/594,596

Applicant(s)

ANDERSEN ET AL.

Examiner

Lisa B. Arthur

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_.

Art Unit: 1634

1. This action is in response to the paper filed April 17, 2002. Currently, claims 1-9 are pending, but claims 2-8 have been withdrawn from prosecution by the restriction requirement made in paper number 3 mailed October 3, 2001. The action includes an examination of Group 1. Any rejections which have not been reiterated have been withdrawn. All of the arguments and amendments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow. This action is FINAL.

**MAINTAINED REJECTIONS**

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility. The claimed nucleic acid is not supported by a specific asserted utility because the specification only states that the cDNA compound is useful as a probe for obtaining the full length coding sequence or the gene, which would be used to make protein. Once the protein was obtained, the protein would be used in conducting research to functionally characterize the protein. However, a starting material which can only be used to produce a final product of unknown function does not have a specific asserted utility when that final product does not have a specific utility. In this case the protein that would be produced as a final product resulting from processes involving SEQ ID NO 1 has no asserted or otherwise identified specific utility. The research contemplated by Applicant to establish utility for a potential protein product by elucidating its properties and function of the protein has not been specified and does not constitute a

Art Unit: 1634

specific utility. The specification does not describe any other specific use for SEQ ID NO 1. Also, because the claimed invention is not supported by a specific asserted utility for the reasons given above, credibility can not be assessed. Neither the specification nor any art of record discloses or suggests an activity for SEQ ID NO 1 such that another non-asserted utility would be well-established.

***Response to arguments***

The response asserts that the examiner acknowledged a utility as being using the cDNA compounds as a probe for obtaining full length coding sequences which could be used to make a protein. This argument has been reviewed but is not convincing because the examiner acknowledged that the specification asserts that this is an asserted utility but then states that this asserted utility is a general utility not a specific and substantial utility as is required by the utility guidelines. A general utility is one that is applicable to a broad class of compounds. For example, any nucleic acid can be used as a probe to detect a full length sequence which can then be used to produce a protein. In contrast, a specific utility is one which is specific to the claimed subject matter. The disclosure of a polynucleotide which encodes a protein that has a specific function would make the use of the polynucleotide as a probe a specific utility. However, in the instant case, the specification provides no information about the functional activity of the encoded polypeptide. All of the uses described in the specification are general utilities because they are uses that a huge number of polynucleotides have on basis that they are polynucleotides rather than on the specific nature of their nucleotide sequence. While the claimed polynucleotide would only

Art Unit: 1634

detect a complementary nucleic acid in a stringent hybridization reaction, there is no disclosed use for the resulting polynucleotide.

The response argues that the examiner states that the credibility of the asserted utilities has been assessed. This argument has been reviewed but is not convincing because the action actually stated that the credibility could not be assessed because there was no specific and substantial utility asserted in the specification for the reasons given above. That is, the use of a nucleic acid as a probe or for chromosomal mapping is credible but it is not specific and substantial because it is a utility which a huge number of nucleic acids possess and is not specific for the disclosed sequence.

The response argues that the action did not provide factual basis for questioning the objective truth of the operability of the asserted utilities. This argument is not convincing because the rejection is based upon the asserted utilities being general utilities rather than being specific and substantial as is required by the utility guidelines. There is no question that the disclosed nucleic acid could be used as a probe to detect itself. However, the detection of this polynucleotide has no real world use because the function of the protein encoded by the nucleic acid has not been described nor has the polynucleotide been associated with a disease or some other immediately useful property.

The response argues that detection of a polymorphism is a specific and substantial utility. This argument is not convincing because the detection of a polymorphisms is not useful until the polymorphisms is associated with a disease or other specific characteristic of interest to the public.

The response argues that the nucleic acid of this invention would detect a unique subset of related sequences which could not be detected by a generic group of probes. This argument is not convincing because while this may be true the artisan would still not have an immediate use for the detected nucleic acids because their encoded protein has not been identified nor has the polynucleotide been associated with a disease or other property. The polynucleotides appear to be useful only for further research to discover these useful properties. Therefore, the nucleic acids of the invention do not have a real world context of use.

4. Claim 1 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Response to Arguments***

The arguments have been thoroughly reviewed but are non-persuasive for the same reasons as given above.

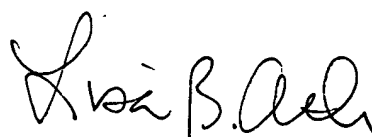
6. No claims are allowable.

7. THIS ACTION IS MADE FINAL. Application is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed with TWO MONTHS of the mailing date of this final action and

Art Unit: 1634

the advisory action is not mailed until after the end of the THREE MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa B. Arthur whose telephone number is (703) 308-3988. The examiner can normally be reached on Monday-Wednesday from 7:00 am to 2:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for the organization where this application or proceeding is assigned is 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.

  
LISA B. ARTHUR  
PRIMARY EXAMINER  
P. CUP 1800-1600

June 26, 2002